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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PHAM, HUNG Q	
ART UNIT	PAPER NUMBER
2168	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/879,382	STOLOFF ET AL.	
	Examiner	Art Unit	
	HUNG Q. PHAM	2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,15,16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/2007 has been entered.

Response to Arguments

- *Specification*

Applicants' arguments with respect to the objection of term processing means have been fully considered and they are persuasive. The objection of the Specification has been withdrawn.

- *Claim Objections*

The objection has been withdrawn in view of the amendment of claim 1.

- *Claim Rejections - 35 USC § 101*

Applicants' arguments with respect to the rejection claims 15, 16 and 18-21 have been fully considered but they are not persuasive. Claims 15, 16 and 18-21 are directed to a system comprising software per se. Software per se is not a series of steps or acts and thus is not a process. Software per se is not a physical article or object and as such is not a machine or manufacture. Software per se is not a combination of substances and therefore is not a

composition of matter. Software per se is not one of the four categories of invention as set forth in 35 U.S.C. § 101. Therefore, claims 15, 16 and 18-21 are non-statutory.

- *Claim Rejections - 35 USC § 112*

The rejections under 35 U.S.C. § 112, first and second paragraph, have been withdrawn in view of the amendment of claims 1, 3 and 15.

- *Claim Rejections - 35 USC § 102 and 103*

Applicant's arguments with respect to the rejection under 35 U.S.C. § 102 and 103 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed[1].

Claim Objections

Claims 5 and 10 are objected to because of the following informalities: *an medical need* ("*a medical need* " is respectfully suggested). Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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[1] The claims are directed to method, apparatus and system for *collecting medical product information* and *medical need information not addressed by available medical products* as recited in the preamble.

Claims 1-7, 9, 10, 15, 16 and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-7, 9 and 10 are directed to a method and apparatus for *collecting medical product information*. This claimed subject matter lacks a practical application of a judicial exception (law of nature, abstract idea, naturally occurring article/phenomenon) since it fails to produce a useful and tangible result. Specifically, the claimed subject matter does not produce a useful result because the claimed subject matter fails to sufficiently reflect at least one practical utility set forth in the preamble and in the descriptive portion of the specification.

More specifically, while the described practical utility (utilities) is (are) directed to *collecting medical product information* and *assisting companies' focus on limitations and challenges in current diagnostic and therapeutic methods in order for them to initiate activities to improve diagnostic techniques and procedures, medical and surgical treatments, improve product designs and develop new products* (Specification, Page 1 Lines 6-10), the claimed subject matter relates ONLY to *selecting the submission indicative of the medical need not addressed by available medical products* as recited in claim 1 and determining medical need not addressed by available medical products as recited in claim 9 (*medical needs not addressed by available medical products related to the medical products may be determined*).

The claimed subject matter does not produce a tangible result because the claimed subject matter fails to produce a result that is limited to having real world value rather than a result that may be interpreted to be abstract in nature as, for example, a thought, a computation, or manipulated data. More specifically, the claimed subject matter provides for *selecting the submission indicative of the medical need not addressed by available medical products* as recited in claim 1 and determining medical need not addressed by available medical products as recited in claim 9

(*medical needs not addressed by available medical products related to the medical products may be determined*). This produced result remains in the abstract and, thus, fails to achieve the required status of having real world value.

Claims 15, 16 and 18-21 are directed to a system for *collecting medical need information not addressed by available medical products*. This claimed subject matter lacks a practical application of a judicial exception (law of nature, abstract idea, naturally occurring article/phenomenon) since it fails to produce a useful, concrete and tangible result.

Specifically, the claimed subject matter does not produce a useful result because the claimed subject matter fails to sufficiently reflect at least one practical utility set forth in the descriptive portion of the specification. More specifically, while the described practical utility (utilities) is (are) directed to *assisting companies' focus on limitations and challenges in current diagnostic and therapeutic methods in order for them to initiate activities to improve diagnostic techniques and procedures, medical and surgical treatments, improve product designs and develop new products* (Specification, Page 1 Lines 6-10), the claimed subject matter relates ONLY to identifying a submitted medical need not addressed by available medical product (*submitted medical need not addressed by available medical products for development of a medical product related to the categorized submission may be identified*).

The claimed subject matter does not produce a tangible result because the claimed subject matter fails to produce a result that is limited to having real world value rather than a result that may be interpreted to be abstract in nature as, for example, a thought, a computation, or manipulated data. More specifically, the claimed subject matter provides for identifying a submitted medical need not addressed by available medical product (*submitted medical need not addressed by available medical products for development of a medical product related to the categorized submission may be identified*). This produced result remains in the abstract and, thus, fails to achieve the required status of having real world value.

Claims 15, 16 and 18-21 are direct to a system comprising software per se. Software per se is not one of the four categories of invention. Therefore, claims 15, 16 and 18-21 are non-statutory. Software per se is not a series of steps or acts and thus is not a process. Software per se is not a physical article or object and as such is not a machine or manufacture. Software per se is not a combination of substances and therefore is not a composition of matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 15 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As in claims 1 and 15, the claimed limitations, *selecting the submission indicative of the medical need not addressed by available medical products for development of a medical product related to the selected medical need not addressed by available medical products where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic,* and *a submitted medical need not addressed by available medical products for development of a medical product related to the categorized submission may be identified where the submitted medical need not addressed by*

available medical products matches a predetermined number of other submissions having the same primary topic, were not described in the specification[2].

As in claims 6 and 20, the claimed limitation, *an invention submission disclosure form is transmitted to the user that submitted the medical need not addressed by available medical products and the solution to the medical need not addressed by available medical products*, was not described in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As in claim 3, the clause, *the unmet need submissions*, references to other items in the claims. It is unclear what item is being referenced.

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[2] As illustrated in paragraph 34, after submission data is categorized, unmet needs of interest may be identified based a threshold and the number of submission with respect to a particular category, e.g., the number of submission exceeds the threshold. Neither paragraph 34, nor the specification describes the step of *selecting the submission indicative of the medical need not addressed by available medical products for development of a medical product related to the selected medical need not addressed by available medical products where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic.*

As in claim 5, the clause, *the medical need not addressed by available medical products*, references to a plurality of *a medical need not addressed by available medical products* in the claims. It is unclear what item is being referenced.

As in claim 7, the clause, *the unmet need input*, references to other items in the claims. It is unclear what item is being referenced.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 15, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedWatch [The FDA Medical Products Reporting Program] and Classen [USP 6,219,674 B1].

Regarding claims 1 and 15, wherein the claim limitations of claim 15 is being treated under 35 U.S.C. § 112, sixth paragraph, MedWatch is a Medical Products Reporting Program hosted by FDA ***for collecting medical product information*** and ***medical need not addressed by available medical products*** (MedWatch, Page 2, the purpose of MedWatch is to monitor medical products by collecting reports), comprising:

providing a web site having information about medical products (MedWatch, Page 1);

accepting on said web site a submission indicative of a medical need not addressed by available medical products relating to the medical products from a plurality of users (As indicated at Page 9 of MedWatch, Health Professionals as *users* can *summit* Adverse Events Report and Product Problems Report with all Medical Products to MedWatch on *the web site*. As defined at pages 11-14 of MedWatch, any undesirable experience associated with the use of a medical product in a patient or a concern about the quality, performance or safety of any medication or device could be reported, e.g., reporting a Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or reporting a complaint about foul odor coming from the product when it open. The examples of report indicate *a medical need not addressed by available medical products relating to the medical products*);

categorizing the submission indicative of the medical need not addressed by available medical products according to a primary topic (As indicated at Page 9 of MedWatch, a report, e.g., Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or a complaint about foul odor coming from the product when it open, as *the submission indicative of the medical need not addressed by available medical products* is categorized under *a primary topic*, e.g., Adverse Events or Product Problems).

The missing of MedWatch is the step of *selecting the submission indicative of the medical need not addressed by available medical products for development of a medical product related to the selected medical need*

not addressed by available medical products where the submitted medical need not addressed by available medical products matches a predetermined number of other submissions having the same primary topic.

Classen discloses a method for using product data to enhance the safety of a medical product (Classen, Abstract) by analyzing Adverse Event data from MedWatch (Classen, Col. 7 Lines 10-12). Classen further discloses an Adverse Event corresponding to a product as discussed above with respect to the teaching of MedWatch or ***submission indicative of the medical need not addressed by available medical products*** could be risk/benefit analyzed if a single newly discovered Adverse Event ***matches a predetermined number of other submissions having the same primary topic***, e.g., 10 new similar Adverse Events relating to the product may be observed, but none or the individual new Adverse Event occurs more than once in 10,0000 persons (Classen, Col. 9 Lines 10-34), and the purpose is ***for development of a medical product related to the selected medical need not addressed by available medical products***, e.g., seeking patent protection for new therapeutic uses for existing products (Col. 10 Lines 34-57).

The method of analyzing the Adverse Events is a must for MedWatch in order to analyze risk and benefit of a particular medical product with respect to newly Adverse Event.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include the technique of analyzing Adverse Events as taught by Classen into MedWatch method in order to enhance the effectiveness of post-marketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

Regarding claim 9, MedWatch is a Medical Products Reporting Program hosted by FDA ***for collecting medical product information*** (MedWatch, Page 2, the purpose of MedWatch is to monitor medical products by collecting reports), comprising:

a computer hosting a web site wherein the web site stores information about medical products (MedWatch, Page 1 is a *web site stores information about medical products*, the *computer* that *host* the web site of Page 1 is an inherited feature), ***information about the medical products being electronically searchable and browseable*** (*information about the medical product*s, e.g., Case Studies at Pages 19-21, is *searchable and browseable* via TABLE OF CONTENTS of Pages 17-18);

a network connection whereby web pages are delivered to a remote computer and input is accepted from the remote computer (Internet is *a network connection*, *whereby web pages* as in Pages 1 and 4 are *delivered to* a consumer a heath professional with *a remote computer*, and with a conventional browser, *input is accepted from the remote computer*), ***the network accepting an electronic submission indicative of a medical need not addressed by available medical products for the medical products*** (As indicated at Page 9 of MedWatch, Health Professionals as *users* can *summit* Adverse Events Report and Product Problems Report with all Medical Products to MedWatch on *the web site*. As defined at pages 11-14 of MedWatch, any undesirable experience associated with the use of a medical product in a patient or a concern about the quality, performance or safety of any medication or device could be reported, e.g., reporting a Life-Threatening if the patient is at substantial risk of dying if the use of product is continued or reporting a complaint about foul odor coming from the product when it open. The examples of report indicate *a medical need not addressed by available medical products relating to the medical products*).

The missing of MedWatch is the claimed limitation, *medical needs not addressed by available medical products related to the medical products may be determined for the development of a medical product related to the medical need not addressed by available medical products*.

Classen discloses a method for using product data to enhance the safety of a medical product (Classen, Abstract) by analyzing Adverse Event data from MedWatch (Classen, Col. 7 Lines 10-12). Classen further discloses an Adverse Event corresponding to a product as discussed above with respect to the teaching of MedWatch or ***submission indicative of the medical***

need not addressed by available medical products could be risk/benefit determined (Classen, Col. 9 Lines 10-34), and the purpose is ***for development of a medical product related to the selected medical need not addressed by available medical products***, e.g., seeking patent protection for new therapeutic uses for existing products (Col. 10 Lines 34-57).

The method of analyzing the Adverse Events is a must for MedWatch in order to analyze risk and benefit of a particular medical product with respect to newly Adverse Event.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include the technique of analyzing Adverse Events as taught by Classen into MedWatch method in order to enhance the effectiveness of post-marketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.

Regarding claims 2 and 16, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further discloses ***the categorization is done performed by each said plurality of users electronically selecting a category*** (MedWatch, Page 7).

Regarding claim 3, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claim 1, MedWatch further discloses the step of ***filtering the unmet need submissions*** (MedWatch Page 19, three deaths from 50 reports are filtered).

Regarding claims 4 and 18, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further

disclosed ***a gatekeeper such that the gatekeeper filters out input that relates to product complaints*** is provided (MedWatch Page 13, product complaint is filtered out for further investigation).

Regarding claims 5 and 19, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, MedWatch further discloses the step of ***providing a gatekeeper such that the gatekeeper filters out input that describes an medical need not addressed by available medical products and a solution to the medical need not addressed by available medical products*** (MedWatch Page 19, TEMAFLOXACIN is withdrawn from market based on the reports).

Regarding claims 6 and 20, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 5 and 19, MedWatch further discloses ***an invention submission disclosure form is transmitted to the user that submitted the medical need not addressed by available medical products and the solution to the medical need not addressed by available medical products*** (MedWatch, The Privacy Statement at Page 1 as *an invention submission disclosure form* is transmitted to the user using hyperlink).

Regarding claim 7, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1, MedWatch further discloses the step of ***providing a computer implemented medical products information web site in conjunction with the unmet needs input such that users can input medical need not addressed by available medical products while obtaining medical products information*** (MedWatch, Pages 5 and 19).

Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedWatch [The FDA Medical Products Reporting Program] and Classen [USP 6,219,674

B1] and further in view of drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled].

Regarding claim 10, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claim 9, but does not teach ***a medical products purchasing database whereby a user can purchase medical products in conjunction with the submission of an medical need not addressed by available medical products submission***.

Drugstore is a web site for purchasing medical products and has a medical products purchasing database, and by including a hyperlink to Drugstore, Adverse Events can be submitted in conjunction with a medical product purchasing.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include a hyperlink to Drugstore in order to order a medical product online.

Regarding claim 21, MedWatch and Classen, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1, MedWatch and Classen does not explicitly discloses the step of ***providing a computer implemented medical products purchasing web site*** in conjunction with MedWatch such that ***a medical products ordering is processed*** during inputting Adverse Events.

Drugstore is a web site for purchasing medical products and by including a hyperlink to Drugstore, Adverse Events can be inputted during processing a medical product ordering.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to include a hyperlink to Drugstore in order to order a medical product online.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUNG Q. PHAM whose telephone number is 571-272-4040. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIM T. VO can be reached on 571-272-3642. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUNG Q PHAM
Examiner
Art Unit 2168

March 1, 2007